

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

<b>IN RE:</b>	<b>LATEX GLOVE PRODUCTS LIABILITY LITIGATION</b>	:	<b>MDL DOCKET NO. 1148</b>
		:	
		:	
<b>JOANN KAE SMITH</b>		:	<b>THIS DOCUMENT RELATES</b>
		:	<b>ONLY TO CIVIL ACTION</b>
	<b>Plaintiff</b>	:	<b>NO. 02-3806</b>
		:	
	<b>vs.</b>	:	
		:	
<b>ALLEGIANCE CORPORATION, an Illinois Corporation, et al.</b>		:	
	<b>Defendants</b>	:	

**MEDLINE INDUSTRIES, INC.'S ANSWER AND  
AFFIRMATIVE DEFENSES TO PLAINTIFF'S COMPLAINT**

Defendant, Medline Industries, Inc., (hereinafter "Medline"), files its Answer and Affirmative Defenses to Plaintiff's Complaint ("Complaint") as follows:

**ANSWER**

1-9. Medline is without knowledge or information sufficient to form a belief as to the truth of the averments contained in paragraphs 1-9 of the Complaint.

10. Medline admits that it is a corporation incorporated under the laws of the State of Illinois with its principal place of business in Mundelein, Illinois.

11-26. Medline is without knowledge or information sufficient to form a belief as to the truth of the averments contained in paragraphs 11-26 of the Complaint.

27 - 31. Paragraphs 27 - 31 of the Complaint contain legal conclusions to which no answer is required. Insofar as paragraphs 27 - 31 of the Complaint contain allegations of fact, Medline denies each and every allegation that pertains to it. With respect to the remaining averments, Medline is without knowledge or information sufficient to form a belief as to the truth of the averments in paragraphs 27 - 31 of the Complaint.

32. Medline incorporates all of its responses to the previous paragraphs.

33 – 34. Medline denies that it manufactured latex and/or rubber gloves. Medline was a packager, distributor and sterilizer of latex and/or rubber gloves. Paragraphs 33-34 of the Complaint contain legal conclusions to which no answer is required. Insofar as paragraphs 33-34 contain allegations of fact, Medline denies each and every allegation that pertains to it. With respect to the remaining averments, Medline is without knowledge or information sufficient to form a belief as to the truth of the averments in paragraphs 33-34 of the Complaint.

35 - 36. Paragraphs 35 - 36 of the Complaint contain legal conclusions to which no answer is required. Insofar as paragraphs 35 - 36 contain allegations of fact, Medline denies each and every allegation that pertains to it. With respect to the remaining averments, Medline is without knowledge or information sufficient to form a belief as to the truth of the averments in paragraphs 35 - 36 of the Complaint.

37. Medline denies that it manufactured latex and/or rubber gloves. Medline was a packager, distributor and sterilizer of latex and/or rubber gloves. Paragraph 37 of the Complaint

contain legal conclusions to which no answer is required. Insofar as paragraph 37 contain allegations of fact, Medline denies each and every allegation that pertains to it. With respect to the remaining averments, Medline is without knowledge or information sufficient to form a belief as to the truth of the averments in paragraph 37 of the Complaint.

38 - 39. Medline denies that it manufactured latex and/or rubber gloves. Medline was a packager, distributor and sterilizer of latex and/or rubber gloves. Paragraphs 38 - 39 of the Complaint contain legal conclusions to which no answer is required. Insofar as paragraphs 38 – 39 contain allegations of fact, Medline denies each and every allegation that pertains to it. With respect to the remaining averments, Medline is without knowledge or information sufficient to form a belief as to the truth of the averments in paragraphs 38 – 39 of the Complaint.

40. Medline incorporates all of its responses to the previous paragraphs.

41 – 43. Medline denies that it manufactured latex and/or rubber gloves. Medline was a packager, distributor and sterilizer of latex and/or rubber gloves. Paragraphs 41 - 43 of the Complaint contain legal conclusions to which no answer is required. Insofar as paragraphs 41 – 43 contain allegations of fact, Medline denies each and every allegation that pertains to it. With respect to the remaining averments, Medline is without knowledge or information sufficient to form a belief as to the truth of the averments in paragraphs 41 – 43 of the Complaint.

44. Paragraph 44 of the Complaint contains legal conclusions to which no answer is required. Insofar as paragraph 44 contains allegations of fact, Medline denies each and every

allegation that pertains to it. With respect to the remaining averments, Medline is without knowledge or information sufficient to form a belief as their truth.

45. Medline incorporates all of its responses to the previous paragraphs.

46 – 47. Paragraphs 46 – 47 of the Complaint contains legal conclusions to which no answer is required. Insofar as paragraphs 46 - 47 contains allegations of fact, Medline denies each and every allegation that pertains to it. With respect to the remaining averments, Medline is without knowledge or information sufficient to form a belief as their truth.

48. Medline denies that it manufactured latex and/or rubber gloves. Medline was a packager, distributor and sterilizer of latex and/or rubber gloves. Paragraph 48 of the Complaint contain legal conclusions to which no answer is required. Insofar as paragraph 48 contain allegations of fact, Medline denies each and every allegation that pertains to it. With respect to the remaining averments, Medline is without knowledge or information sufficient to form a belief as to the truth of the averments in paragraph 48 of the Complaint.

49. Paragraph 49 of the Complaint contains legal conclusions to which no answer is required. Insofar as paragraph 49 contains allegations of fact, Medline denies each and every allegation that pertains to it. With respect to the remaining averments, Medline is without knowledge or information sufficient to form a belief as their truth.

50. Medline incorporates all of its responses to the previous paragraphs.

51 - 52. Medline denies the truth of the averments contained in paragraphs 51 - 52 of the Complaint.

53 – 56. Paragraphs 53 – 56 of the Complaint contains legal conclusions to which no answer is required. Insofar as paragraphs 53 - 56 contains allegations of fact, Medline denies each and every allegation that pertains to it. With respect to the remaining averments, Medline is without knowledge or information sufficient to form a belief as their truth.

57 – 59. Medline denies that it manufactured latex and/or rubber gloves. Medline was a packager, distributor and sterilizer of latex and/or rubber gloves. Paragraphs 57 - 59 of the Complaint contain legal conclusions to which no answer is required. Insofar as paragraphs 57 - 59 contain allegations of fact, Medline denies each and every allegation that pertains to it. With respect to the remaining averments, Medline is without knowledge or information sufficient to form a belief as to the truth of the averments in paragraphs 57 - 59 of the Complaint.

60 – 61. Paragraphs 60 – 61 of the Complaint contains legal conclusions to which no answer is required. Insofar as paragraphs 60 - 61 contains allegations of fact, Medline denies each and every allegation.

62. Medline incorporates all of its responses to the previous paragraphs.

63. Medline was a packager, distributor and sterilizer of latex and/or rubber gloves.

Paragraph 63 of the Complaint contains legal conclusions to which no answer is required. Insofar as paragraph 63 contains allegations of fact, Medline denies each and every allegation that pertains to it. With respect to the remaining averments, Medline is without knowledge or information sufficient to form a belief as to the truth of the averments in paragraph 63 of the Complaint.

64 - 67. Paragraphs 64 - 67 of the Complaint contain legal conclusions to which no answer is required. Insofar as paragraphs 64 - 67 contain allegations of fact, Medline denies each and every allegation that pertains to it. With respect to the remaining averments, Medline is without knowledge or information sufficient to form a belief as to the truth of the averments in paragraphs 64 – 67 of the Complaint.

68. Medline incorporates all of its responses to the previous paragraphs.

69 – 72. Paragraphs 69 - 72 of the Complaint contain legal conclusions to which no answer is required. Insofar as paragraphs 69 - 72 contain allegations of fact, Medline denies each and every allegation that pertains to it. With respect to the remaining averments, Medline is without knowledge or information sufficient to form a belief as to the truth of the averments in paragraphs 69 – 72 of the Complaint.

73. Medline incorporates all of its responses to the previous paragraphs.

74 - 75. Paragraphs 74 - 75 of the Complaint contain legal conclusions to which no answer is required. Insofar as paragraphs 74 - 75 contain allegations of fact, Medline denies each and every allegation that pertains to it. With respect to the remaining averments, Medline is without knowledge or information sufficient to form a belief as to the truth of the averments in paragraphs 74 - 75 of the Complaint.

76. Medline incorporates all of its responses to the previous paragraphs.

77 - 78. Paragraphs 77 - 78 of the Complaint contain legal conclusions to which no answer is required. Insofar as paragraphs 77 - 78 contain allegations of fact, Medline denies each and every allegation that pertains to it. With respect to the remaining averments, Medline is without knowledge or information sufficient to form a belief as to the truth of the averments in paragraphs 77 - 78 of the Complaint.

79. Medline incorporates all of its responses to the previous paragraphs.

80 - 84. Paragraphs 80 - 84 of the Complaint contain legal conclusions to which no answer is required. Insofar as paragraphs 80 - 84 contain allegations of fact, Medline denies each and every allegation that pertains to it. With respect to the remaining averments, Medline is without knowledge or information sufficient to form a belief as to the truth of the averments in paragraphs 80 - 84 of the Complaint.

85. Medline incorporates all of its responses to the previous paragraphs.

86 – 93. Paragraphs 86 - 93 of the Complaint contain legal conclusions to which no answer is required. Insofar as paragraphs 86 – 93 contain allegations of fact, Medline denies each and every allegation that pertains to it. With respect to the remaining averments, Medline is without knowledge or information sufficient to form a belief as to the truth of the averments in paragraphs 86 – 93 of the Complaint.

#### **FIRST AFFIRMATIVE DEFENSE**

The Complaint fails to state a claim upon which relief can be granted against Medline.

#### **SECOND AFFIRMATIVE DEFENSE**

Some or all of the claims against Medline are barred by the doctrine of contributory/comparative negligence.

#### **THIRD AFFIRMATIVE DEFENSE**

Any injuries or damages sustained by plaintiffs were caused, in whole or in part, by plaintiff Joann Kae Smith's acts or omissions.

#### **FOURTH AFFIRMATIVE DEFENSE**

Plaintiffs have failed to exercise proper and reasonable care to mitigate the damages averred in this action.

#### **FIFTH AFFIRMATIVE DEFENSE**



If plaintiffs sustained the injuries or incurred the expenses alleged, the same may have been caused, in whole or in part, by operation of nature or by act of God.

**SIXTH AFFIRMATIVE DEFENSE**

If plaintiffs incurred loss, damage, injury, harm, expense, diminution or deprivation, this may have been caused by the plaintiff Joann Kae Smith's idiosyncratic reaction without negligence, strict liability, or lack of care or any other breach of duty on the part of Medline.

**SEVENTH AFFIRMATIVE DEFENSE**

The perils and dangers of which plaintiffs complain, to the extent they exist, which Medline denies, were open and obviously known to plaintiffs, who nevertheless conducted themselves in such a manner as to expose themselves to said perils and dangers.

**EIGHTH AFFIRMATIVE DEFENSE**

If in fact plaintiffs were damaged in any manner whatsoever, said damages, if any, were a direct and proximate result of the intervening and supervening conduct on the part of other named or unnamed parties, including plaintiff, Joann Kae Smith, and her employers/agents, over whom Medline has no control, and such intervening and superseding conduct of said other parties was the sole legal cause of any injury or damage to plaintiffs and bars recovery against Medline.

**NINTH AFFIRMATIVE DEFENSE**

Over time, as the level of knowledge regarding possible risks of adverse reactions to latex gloves and other latex containing products used in the health care field developed, that information

was widely disseminated and generally known to health care workers. Joann Kae Smith, as an alleged Certified Nurse Assistant and an alleged Licensed Practical Nurse, is familiar with natural rubber latex gloves and sophisticated in her understanding of allergic reactions.

#### **TENTH AFFIRMATIVE DEFENSE**

There is no reasonable way of foretelling who will suffer an adverse reaction to latex gloves or other latex containing products used in the health care field.

#### **ELEVENTH AFFIRMATIVE DEFENSE**

If any loss, damage, injury, harm, expense, diminution, or deprivation alleged by plaintiffs were caused by any product distributed by Medline, which Medline denies, Medline is entitled to a reduction in any damages awarded which are attributable to the plaintiff's misuse of the product by continuing to use or to be exposed to latex gloves, despite being an alleged cause of her symptoms.

#### **TWELFTH AFFIRMATIVE DEFENSE**

Plaintiff voluntarily assumed the risk of injury to herself because she had knowledge of, understood and appreciated the risks and dangers, if any, incident to the use of natural rubber latex gloves and other latex containing products used in the health care field.

#### **THIRTEENTH AFFIRMATIVE DEFENSE**

The methods, standards, and techniques utilized in Medline's natural rubber latex gloves, and in issuing warnings and any instructions with respect to use, conformed with the generally recognized, reasonably available, and reliable state of medical and scientific knowledge at the time

the gloves were distributed or sold, and conformed to the state of the art for the design and labeling of similar products.

**FOURTEENTH AFFIRMATIVE DEFENSE**

After any alleged products left the possession and control of Medline and without Medline's knowledge or approval, the alleged product was re-designed, modified, altered, incorporated into a finished product, or subjected to treatment that substantially changed its character. The defect in any alleged product, as alleged in the Complaint, resulted, if at all, from the redesign, modification, alteration, treatment, or other change of the product after Medline relinquished possession and control over any alleged product and not from any act or omission of Medline.

**FIFTEENTH AFFIRMATIVE DEFENSE**

The latex gloves at issue were fit and proper for their intended purpose and the social utility of the gloves or related equipment outweighs any possible risk inherent in the use of this product.

**SIXTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred because of the lack of privity between plaintiffs and Medline.

**SEVENTEENTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred because plaintiff was a sophisticated user of latex rubber gloves and, therefore, no duty existed for Medline to warn plaintiff of any potential risk associated with the use of latex rubber gloves.

**EIGHTEENTH AFFIRMATIVE DEFENSE**

Any duty to warn plaintiff of the risks and hazards associated with the subject product was discharged by providing adequate warning to physicians and receiving hospitals and health care facilities, and therefore, the learned intermediary doctrine bars recovery of any damages.

**NINETEENTH AFFIRMATIVE DEFENSE**

If plaintiff has been injured by latex gloves, the gloves are deemed to be an "inevitably unsafe" product as defined in comment(k), section 402A of the Restatement of Torts(2d) and, at all relevant times, the gloves were not unreasonably dangerous given the state of knowledge regarding such product and, as such, strict liability in tort does not apply to latex gloves, all of which precludes the imposition of strict liability against Medline.

**TWENTIETH AFFIRMATIVE DEFENSE**

Latex gloves are neither defective nor unreasonably dangerous because they are medical devices falling within what is commonly known as "comment (j)" in the Restatement (2d) of Torts, section 402A, in that latex gloves were, at all times material to plaintiff's Complaint, reasonably safe, and reasonably fit for their intended use, and the warnings and instructions accompanying latex gloves at the time of the occurrence or injuries alleged by plaintiff were legally adequate.

**TWENTY-FIRST AFFIRMATIVE DEFENSE**

Plaintiffs have failed to give proper and timely notice of their claims of breach of warranty and have failed to comply with the Commercial Code.

**TWENTY-SECOND AFFIRMATIVE DEFENSE**

Plaintiffs' claims against Medline, if any, are barred, in whole or in part, by the applicable statute of limitations and the doctrines of laches, waiver and estoppel.

**TWENTY-THIRD AFFIRMATIVE DEFENSE**

The granting of relief prayed for in plaintiffs' Complaint is unconstitutional under the United States Constitution in that it violates Due Process and Equal Protection guarantees, places an undue burden on interstate commerce, violates constitutional proscriptions against excessive fines, and violates applicable state statutes, policies, and common law.

**TWENTY-FOURTH AFFIRMATIVE DEFENSE**

The causes of action averred in the Complaint are preempted, in whole or in part, by applicable federal and state law.

**TWENTY-FIFTH AFFIRMATIVE DEFENSE**

Venue is improper.

**TWENTY-SIXTH AFFIRMATIVE DEFENSE**

For the convenience of parties and witnesses, in the interest of justice, venue should be transferred.

**TWENTY-SEVENTH AFFIRMATIVE DEFENSE**

Medline's liability, if any, to plaintiffs is limited, in whole or in part, by applicable state law restricting the liability of parties who did not manufacture the goods involved in the action.

**TWENTY-EIGHTH AFFIRMATIVE DEFENSE**

Plaintiff lacks standing to sue for causes of action assigned to the Department of Labor and Industries.

**TWENTY-NINTH AFFIRMATIVE DEFENSE**

Plaintiff has elected not to proceed against the defendants.

**THIRTIETH AFFIRMATIVE DEFENSE**

Plaintiff has failed to join parties under Fed. R. Civ. P. 19.

**WHEREFORE**, Medline respectfully demands that judgment be entered in its favor and against plaintiffs, together with costs, and that Medline be granted any additional relief to which it may be entitled.

**JANSSEN & KEENAN P.C.**

**By:**

HENRY H. JANSSEN, ESQUIRE  
KENNETH JAY GRUNFELD, ESQUIRE  
Attorneys for Defendant  
Medline Industries, Inc.

**Dated:** \_\_\_\_\_

**CERTIFICATE OF SERVICE**

The undersigned hereby certified that true and correct copies of the foregoing **Answer and Affirmative Defenses of Defendant, Medline Industries, Inc., to Plaintiffs' Complaint** were served on the date set forth below via First Class Mail, U.S. postage prepaid, on the following counsel and parties:

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Dated: \_\_\_\_\_